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Technical Bulletin F2-11Amended

TO: Regional EPHS V's
Local Public Health Administrators
Local Environmental Public Health Specialists

FROM: Mark Jenkerson, Chief
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SUBJECT: Recall Procedures

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Introduction

A recall is a firm's voluntary removal of a product from commerce or consumer channels to protect the public from consuming adulterated or misbranded products. Generally, recalls are conducted on a firm's own initiative by Food and Drug Administration (FDA) request or, in the case of meat and poultry products, by the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS).

DHSS will not announce a recall until the announcement appears on the FDA or USDA website; or until the recall is received through official means of notification by the recalling agency. Once DHSS receives official information regarding a recall, that information, along with the expected recall activities, will be provided to the local public health agencies (LPHAs).

The manufacturer or distributor may choose to issue a press release to announce the recall and/or call their customers directly prior to the issuance of, or simultaneously with the issuance of, a press release. In addition, there may be announcements regarding the recall on various "list-serves" on the Internet**.**

Communications and information sharing with other state agencies that are involved with regulating recalled product within the state is critical to the health of the public. The Department of Health and Senior Services (DHSS) will work cooperatively with these other state agencies when there is a recalled product within the state. DHSS staff will assist in recall investigation at the request of other agencies or when the recall is statewide.

Three Classifications of Recalls

There are three general classes of recalls that are recognized by federal agencies with jurisdiction over the nation's food supply. Each classification is explained in detail below:

Class I - Dangerous or defective products that predictably could cause serious health problems or death. Examples include: food found to contain botulism toxin; the presence of the bacteria *Listeria monocytogenes* in ready-to-eat meats and cheeses; food with undeclared allergens; or a label mix-up on a lifesaving drug. All Class I food recalls will be posted on DHSS web page to make the information accessible to the public and DHSS will develop a press release as appropriate.

Class II - Products that might cause temporary health problems or pose only a slight threat of a serious nature. Examples include: a drug that is under-strength but that is not used to treat life-threatening conditions; the presence of FD&C Yellow #5 dye in candy; inadequate records; or an industry initiated product withdrawal.

Class III - Products that are unlikely to cause any adverse health reaction but that violate FDA labeling or manufacturing laws. Examples include: a minor container defect and lack of English labeling in a retail food or the addition of water to a processed meat without listing the water on the label as required by federal regulations.

Response Activities

Food product recalls in Missouri will follow the above classification system. Recalls initiated voluntarily by a Missouri firm or at the request of DHSS due to results of an epidemiologic investigation, consumer complaint, or laboratory-sampling results will be placed in one of the above classes based on the hazard level associated with the food.

When the Bureau of Environmental Health Services (BEHS) receives a recall notification, appropriate action will be taken to protect the health of consumers in Missouri.

Actions taken will include the following:

1. Obtain the name of the recalled product, size of containers, lot numbers involved, and production dates;
2. Obtain distribution sites in Missouri and neighboring states;
3. Obtain information regarding any adverse health effects caused by consumption of the product;
4. Provide procedures or direction for proper disposition of the product in Missouri:
    - Recall or disposition of the product relies on direction from the recalling firm, FDA or FSIS. The recalling firm generally provides direction to their customers/vendors as to the proper disposition;
    - The recalling firm will request specifically identified product to be removed from commerce and further direction may request the product to be discarded or returned; and,
5. Provide notification to the local public health agencies through the use of the electronic messaging, the fax system, or via telephone communication. The recall notification will include:
    - Distribution information provided by the recalling firm or federal lead agency; and
    - The action(s) DHSS expects the local public health agency to take as a result of the recall.

Each recall is unique with some having a much greater potential to cause harm for the consuming public than others. Therefore, the response activities for each recall may be different. However, the most common recall activity requested of the LPHAs is a recall effectiveness check. These effectiveness

checks should be documented on the DHSS Recall Follow-up Report Form. These checks are to be performed by a site visit to the facility or by telephone to assure that potentially adulterated products have been removed from commerce. If, during an effectiveness check, a recalled product is available on the shelf for sale, and the firm does not take immediate corrective action, the product should be embargoed and stored in a secured location at the facility.

The following is a brief overview of the expected responses for Class I, II, III recalls of food, drug and medical devices. Additional guidance will be provided on each individual recall notice.

Class I Recall Response Guidance

This class of recall has been further categorized into three potential levels of risk and their appropriate response activities.

1. Class I Recall – HIGH Priority

Situation: A product in distribution has caused severe illness, injury, or death to consumers and may be associated with a widespread foodborne illness outbreak or other situations of critical importance such as botulism toxin being found. Illnesses in Missouri are associated to the outbreak. Examples include any botulism toxin in canned food or a widespread outbreak affecting large numbers of consumers such as recent outbreaks of salmonella in eggs and salmonella in peanut butter products.

Response: This type of Class I recall is the highest priority recall and requires immediate attention and response. There must be a comprehensive, prompt response to the recall assuring the product is removed from distribution. It is expected that the LPHA will take every step necessary to assure the affected food product/drug is removed from commerce. The LPHA should perform the following actions in response to this type of Class I recall:

- Within 24 hours assure press releases, if available, are disseminated to local media channels. Notify all retail food establishments including restaurants, grocers, institutions, food pantries, salvage stores, child care facilities, and other facilities that could have the product by site visit or telephone, fax or email.
- Within two working days of recall notification, conduct onsite effectiveness checks at affected establishments to assure product is removed from commerce. This response may involve supplementing environmental staff by temporarily reassigning communicable disease staff, nutritionists or others to assist in the effort.
- If recalled product is found and the product is still available for the public to purchase, the retailer may remove the product from commerce voluntarily or the recalled product will be embargoed, which effectively removes it from commerce.
- Document findings on the DHSS Food Recall Follow-up Form or the Recall Follow-up Summary Form and send a copy of the completed form to BEHS.

2. Class I Recall – MEDIUM Priority

Situation: A product in distribution has been associated with a foodborne illness or injury or where the potential harm is extreme. None of the associated illnesses are in Missouri. This type of Class I can have

a significant health impact but is less urgent than the High Priority; prompt attention is required. Examples include: Listeria in lunchmeat, E. coli in meat, undeclared allergens associated with illness, or under-processed canned foods without a botulism outbreak.

Response: This type of Class I can have a significant health impact but is less urgent than the High priority; prompt attention is required. The LPHA should perform the following actions in response to this type of Class I Recall:

- Within 24 hours assure press releases, if available, are disseminated to local media channels. Notify all retail food establishments including restaurants, grocers, institutions, food pantries, salvage stores, child care facilities, and other facilities that could have the product by site visit, telephone, fax or email.
- Within three working days of recall notification, conduct effectiveness checks at the affected establishments to assure recall product is removed from commerce. The majority of recall effectiveness checks should be on-site, however, in some instances; a phone call may be acceptable. For example: You have six locations of a national grocery chain in your jurisdiction and historically the company has shown to have excellent recall procedures in place. You might visit three of these stores and call the other three. However, it is prudent to immediately perform on-site effectiveness checks at any salvage stores, small grocery stores, and establishments that, from your experience, have not effectively implemented recall procedures in the past.
- If recalled product is found and is still available for the public to purchase, the retailer may remove the product from commerce voluntarily or the recalled product will be embargoed, which effectively removes it from commerce.
- Document findings on the DHSS Food Recall Follow-up Form or the Recall Follow-up Summary Report Form and send a copy of the completed form to BEHS.

3. Class I Recall – LOW Priority

Situation: A product in distribution has been found by laboratory testing to contain pathogens or undeclared allergens with no reported illnesses or adverse reactions.

Response: This type of Class I recall remains very important, however the urgency is not as great as seen in the other types of Class I recalls. If local resources can support it, a response identical to that described for Medium Priority recalls is ideal. At a minimum, the LPHA should perform the following actions in response to this type of Class I Recall:

- Assure press releases are disseminated to local media channels. Notify all retail food establishments including restaurants, grocers, institutions, food pantries, salvage stores, child care facilities, and other food establishments that could have the product by site visit, telephone fax or email.
- Conduct effectiveness checks during routine inspections, and as time allows, at potentially affected establishments. Often, the effectiveness checks may be completed by telephone. Firms with a poor track record of complying with recall notifications should have an on-site effectiveness check.

- If recalled product is found and is still available for the public to purchase, the retailer may remove the product from commerce voluntarily or the recalled product will be embargoed, which effectively removes it from commerce.
- Document findings on the DHSS Recall Follow-up Form or the Recall Follow-up Summary Report Form and send a copy of the completed report to BEHS.

Class II and Class III Recall Response Guidance

These recalls have less of a public health impact; however, it is important to provide the public and food establishments with information related to these recalls. Examples include: a drug that is under-strength but that is not used to treat life-threatening conditions; the presence of FD&C Yellow #5 dye in candy; inadequate records; or an industry initiated product withdrawal. Unless otherwise notified, the recall information will be provided to the LPHA primarily for informational purposes with the expectation that the LPHA should perform effectiveness checks during routine inspections. The recall information will be posted to the DHSS Web site.

Drug Recall Response Guidance

The DHSS has the authority and the responsibility to assure that adulterated and misbranded drugs are removed from commerce. Recalls of prescription (Rx) drugs will be posted on DHSS's web page to make the information accessible to the public. Because prescription drugs are issued by licensed professionals effectiveness checks are not a standard procedure for LPHA's.

Duties of BEHS Staff:

1. Staff will serve on a recall team as assembled by the Section for Environmental Public Health (SEPH) or BEHS. A Recall Leader will be designated and the Recall Leader will act as a liaison with LPHAs, federal agencies, other state agencies as necessary, and within DHSS. Staff will assist the FDA, FSIS or other state agencies with jurisdictional responsibilities in their ongoing investigations.
2. Staff will contact product distributors to determine the presence and the amount of the recalled product in Missouri and assist in determining the extent of distribution of product in Missouri.
3. All staff involved in the recall will maintain ongoing communication with the designated Recall Leader. The Recall Leader will provide direction for notification to LPHAs regarding recall status, any changes in classification, and additional products involved, etc.
4. The Recall Leader will notify the Section Administrator and Division Director's Office, Center for Local Public Health, BEHS staff, Bureau of Communicable Disease Control (BCDCP), other involved state agencies, as well as, all LPHAs via internet, fax, or telephone of the occurrence of the recall and the expected action that the LPHA should take in response to the recall, such as embargos and effectiveness checks.
5. All technical staff will provide assistance to Local Public Health Agency staff.
6. Staff will direct embargo of recalled product as necessary.
7. The Recall Leader will assist the Office of Public Information and the Director's office in developing press releases as necessary.

8. Staff will respond to consumer inquiries regarding the adverse health effects if a recalled product is consumed. This information will be contained in the recall announcement itself or can be obtained from the local communicable disease coordinator.
9. If the recalled product was manufactured in Missouri under the jurisdiction of DHSS, BEHS will conduct an investigation of the facility to assure compliance with good manufacturing practices. Any recalled product in inventory at the facility will be embargoed as necessary.
10. If the recalled product was manufactured in Missouri under the jurisdiction of Missouri Department of Agriculture (MDA), DHSS staff will conduct joint investigations within the processing facility under MDA jurisdiction and at the request of MDA.
11. BEHS will develop and provide a report of recall activities to management.

Common Responsibilities of LPHA

1. Follow the action(s) the DHSS Central Office Staff recommends in the recall notification announcement such as checking retail outlets for the presence of recalled product (effectiveness checks).
2. Respond to consumer inquiries regarding adverse health effects if the recalled product is consumed. This information will be contained in the recall announcement itself or can be obtained from the local communicable disease coordinator.
3. Assure recalled product is removed from commerce; place recalled product under embargo if necessary.
4. Maintain communication with Central Office and regional staff regarding actions taken involving the recalled product.
5. Provide recall follow-up reports as necessary for complete documentation of activities.

Resources

1. Recall Coordinator contact information
Nancy Beyer
Bureau of Environmental Health Services
(573)751-6095
nancy.beyer@health.mo.gov

2. DHSS Recall Web Address:
http://health.mo.gov/safety/foodrecalls/index.php

3. FDA Recall Web Address:
http://www.fda.gov/Safety/Recalls/default.htm

4. USDA Recall Web Address:
http://www.fsis.usda.gov/FSIS_Recalls/Open_Federal_Cases/index.asp